

# Brain imaging responses to food in insulin resistance - screening

<b>Submission date</b> 14/12/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/12/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/03/2018	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Obesity (being very overweight) and health problems related to obesity (including type 2 diabetes) are becoming more common, causing long-term ill health. As yet we do not understand why some people are particularly prone to weight gain and diabetes. One possibility is that people who are more prone to obesity and diabetes have a malfunction in the brain mechanisms that stop their desire to eat more after a meal. Gaining further knowledge of the way the brain controls eating will help the development of new ways to prevent and treat these diseases. The researchers are running a study to look at the way the brain controls appetite by using functional magnetic resonance imaging (fMRI), comparing the results from people who are "insulin resistant" and therefore at a higher risk of developing diabetes with people who are "insulin sensitive" and therefore at a lower risk of developing diabetes. Here, they are screening volunteers to see if they are able to join the study.

### Who can participate?

Men aged between 18-65 years with a body mass index (BMI) of no more than 30 kg/m<sup>2</sup>. Insulin sensitive participants should not have any family history of diabetes mellitus. Insulin resistant subjects must have first degree relatives (i.e. parent, sibling or child) with type 2 diabetes.

### What does the study involve?

All participants are asked to complete a number of questionnaires about their eating habits to check that they don't have an eating disorder. They are also asked to provide their medical history and have a brief physical examination (which includes taking their height, weight, neck and waist measurements). Blood samples are taken after an overnight fast to check that they don't have diabetes and to see how well they respond to insulin. The results of this screening will be used to check of each participant can take part in the next part of the study (see <http://www.isrctn.com/ISRCTN51099878>)

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

King's College Hospital NHS Trust

When is the study starting and how long is it expected to run for?  
December 2010 to November 2013

Who is funding the study?  
Diabetes UK

Who is the main contact?  
Dr Yee Seun Cheah  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Yee Seun Cheah

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## Additional identifiers

**Protocol serial number**  
9515

## Study information

**Scientific Title**  
Brain imaging responses to food in insulin resistance: a single centre non-randomised interventional screening trial

**Acronym**  
DRN 546

**Study objectives**  
Obesity and related health problems including type 2 diabetes are becoming more common, causing long-term ill health. As yet, it is not understood why some people are particularly prone to weight gain and diabetes. One possibility is a malfunction in the brain mechanisms that stop our desire to eat more after a meal in people predisposed to obesity and diabetes. Gaining further knowledge of the way the brain controls eating will help the development of new ways to prevent and treat these diseases.

The project will look at the way the brain controls appetite by using functional magnetic resonance imaging (fMRI). This is a method of taking images of the brain that will allow us to see the activity of brain regions that control eating. Brain responses will be studied after eating in healthy relatives of people with diabetes, who are "insulin resistant", where the body is less responsive to insulin, a hormone normally produced by the body to control sugar (glucose) levels. These people will therefore be at higher risk of developing diabetes and obesity. They will be compared to people who are insulin sensitive, at lower risk of diabetes. The impact of treating insulin resistance on these brain responses will then be investigated. This will allow researchers to see if the brain controls eating differently in those at risk of diabetes and obesity, and whether it can be reversed. The imaging methods that are developed may also permit the early assessment of potential therapies to improve appetite control, aiding the development of new ways to prevent or treat obesity and diabetes in the future.

This screening study will identify appropriate subjects that will enter the subsequent intervention study (<http://www.isrctn.com/ISRCTN51099878>) described above.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

South East London REC3 (formally King's College Hospital REC), 18/06/2010, ref:10/H0808/47a

### **Study design**

Single centre non-randomised interventional screening trial

### **Primary study design**

Interventional

### **Study type(s)**

Screening

### **Health condition(s) or problem(s) studied**

Topic: Diabetes Research Network; Subtopic: Type 2; Disease: Obesity

### **Interventions**

Volunteers will attend a screening visit to determine their eligibility to enter the intervention study (UKCRN 9117; DRN 518; ISRCTN51099878) according to the inclusion criteria. This will include completing validated questionnaires of eating behaviour to exclude the presence of eating disorders. Volunteers will also provide their medical history and undergo a brief physical examination, which will include measurements of their height, weight, neck and waist circumference. Blood samples will be collected after an overnight fast to exclude the presence of diabetes and to establish the degree of insulin sensitivity. The screening process will involve a maximum of 2 visits within a one month period.

Follow-up length: 1 months

Study entry: registration only

### **Intervention Type**

Other

### **Phase**

Not Applicable

**Primary outcome(s)**

Insulin sensitivity and glycaemic status, results of intervention to be available within a maximum of one month of completing screening process

**Key secondary outcome(s)**

Eating behaviour, determined during screening visit

**Completion date**

01/11/2013

**Eligibility**

**Key inclusion criteria**

All subjects (insulin sensitive and insulin resistant):

1. Men
2. Age 18 - 65 years (inclusive at time of recruitment)
3. Right-handed
4. English speaking
5. No active medical illness including diabetes mellitus
6. Body mass index (BMI) less than or equal to 30 kg/m<sup>2</sup>

Insulin sensitive subjects:

7. No family history of diabetes mellitus
8. Insulin sensitive (determined by homeostatic model assessment - insulin resistance [HOMA2-IR] during screening process)

Insulin resistant subjects:

9. First degree relatives of patients with type 2 diabetes mellitus
10. Insulin resistance (determined by HOMA2-IR during screening process)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Male

**Key exclusion criteria**

1. Women
2. Left-handedness

3. Current or past history of significant substance abuse or eating disorder
4. Neurological or psychiatric disorders
5. Use of medication that may affect brain activity (e.g. antidepressants, anticonvulsants, antipsychotic drugs), drugs for obesity (orlistat or sibutramine) or drugs that lower glucose (e.g. metformin, sulphonylureas, thiazolidinediones, incretins or insulin)
6. Inability to understand spoken and/or written English
7. Claustrophobia (because of the small bore of the MR scanner)
8. BMI greater than 30 kg/m<sup>2</sup>
9. Contraindication to MRI (pacemaker in situ, extensive dental work, history of penetrating eye trauma, presence of metal surgical clips etc.)
10. Presence of diabetes

**Date of first enrolment**

01/12/2010

**Date of final enrolment**

01/11/2013

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**King's College London**

10 Cutcombe Road

London

United Kingdom

SE5 9RJ

## **Sponsor information**

**Organisation**

Kings College London (KCL)

**Organisation**

King's College Hospital NHS Foundation Trust

**Organisation**

King's College London

**ROR**

<https://ror.org/0220mzb33>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Diabetes UK

**Alternative Name(s)**

The British Diabetic Association, DIABETES UK LIMITED, British Diabetic Association

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration